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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,400	06/04/2001	Werner G. Kuhr	407T-894701US	5307

22798 7590 06/30/2005

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/874,400

Applicant(s)

KUHR ET AL

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 7 April 2005 in which claims 1 and 10-13 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 7 October 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-21 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 8, 10-19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998).

Regarding Claim 1, Muller et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed to a wall differing first and second analyte-specific binding partners located in different regions of the channel (Column 8, lines 29-54), passing a fluid comprising a sample through the channel for analyte binding, releasing

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the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Column 15, lines 55-67).

Regarding Claim 2, Muller et al disclose the method wherein the analyte (target) is not labeled (i.e. Muller uses detector probes and non-labeled targets Column 5, lines 25-35).

Regarding Claim 3, Muller et al disclose the method wherein the channel is a capillary tube (Column 8, lines 29-33).

Regarding Claim 4, Muller et al disclose the method wherein the capillary tube is a capillary electrophoresis tube (Column 8, lines 29-33).

Regarding Claim 5, Muller et al disclose the method wherein the capillary is an etched surface (Column 9, lines 47-54).

Regarding Claim 6, Muller et al disclose the method wherein the channel is etched in glass (Column 9, lines 47-54).

Regarding Claim 8, Muller et al disclose the method wherein the channel is a plastic surface (Column 14, lines 34-37).

Regarding Claim 10-12, Muller et al disclose the method wherein the channel has a cross-sectional diameter and width of 100 $\mu$ m (Column 14, lines 34-41).

Regarding Claim 13, Muller et al disclose the method wherein the channel comprises a third binding partner attached to the capillary wall i.e. detection of 100 or more different analytes (Column 5, lines 19-21).

Regarding Claim 14, Muller et al disclose the method wherein the binding partners are antibodies, binding proteins or nucleic acids (Column 9, line 65-Column 10, line 18).

Regarding Claim 15, Muller et al disclose the method wherein the binding partners are nucleic acids (Column 8, lines 29-37).

Regarding Claim 16, Muller et al disclose the method wherein the passing a fluid is induced by a pressure difference i.e. introducing fluid via pumping i.e. pressure (Column 15, lines 57-59).

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Regarding Claim 17, Muller et al disclose the method wherein the fluid is passed using electronically controlled fluid flow (Column 14, line 65-Column 15, line 15). While they do not define their flow as electroosmotic, the instant claims and specification do not provide a definition of electroosmotic whereby the methods of Muller are excluded. The specification merely teaches driving the fluids using electroosmotic methods (page 32, lines 15-16). Because Muller et al teach driving the fluid through the capillary using electronic charge, their fluid movement is encompassed by the electroosmotic methods described and claimed.

Regarding Claim 18, Muller et al disclose the method wherein the sample comprises blood, plasma, serum, urine, oral fluid, cerebrospinal fluid and lymph are all well known sample routinely used in immunoassays, enzyme assays and gene-specific assays as taught by Muller et al (Column 10, lines 38-47).

Regarding Claim 19, Muller et al disclose the method wherein detecting comprises absorbance spectroscopy (Column 15, lines 16-24).

Regarding Claim 21, Muller et al disclose the method wherein the targets are nucleic acids and targets are detected at concentrations of less than  $1 \times 10^{-9}M$  ((Column 19, lines 2-4).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998) in view of Wainright et al (U.S. Patent No. 6,306,273, filed 13 April 1999).

Regarding Claim 7, Muller et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed to a wall differing first and second analyte-specific binding partners located in different regions of the channel (Column 8, lines 29-54), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Column 15, lines 55-67).

Muller et al further teach numerous and various surfaces for the channels are known and useful in their method (Column 12, lines 9-16 and Column 14, lines 34-37) but they do not specifically teach ceramic. However, surfaces for channel construction comprising ceramic were well known in the art at the time the claimed invention was made as taught by Wainright et al (Column 23, lines 65-67) who specifically the composition is selected based on particular use, economic concerns, solvent compatibility, optical clarity, color, mechanical strength, dielectric properties and etc (Column 24, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the surface composition of Muller et al by using ceramic based on "particular use" as taught by Wainright (Column 23, line 65-Column 24, line 7). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on functionality of the compositions as taught by Wainright.

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6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998) in view of Yager (U.S. Patent No. 6,007,775, issued 28 December 1999).

Regarding Claim 9, Muller et al are silent regarding a cross-sectional area that provides a Reynold's number of less than about 1. However, it was well known in the art at the time the claimed invention was made that channels having a Reynold's number of less than about 1 were desirable because a low Reynold's number provides laminar flow (see Yager, Column 4, line 59-Column 5, line5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cross-sectional area of Muller's channels to provide a Reynold's number of less than about 1 for the obvious benefits of laminar flow i.e. facilitates analyte diffusion and detection as taught by Yager (Column 4, line 59-Column 5, line 14).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998) in view of Kuhr et al (U.S. Patent No. 5,958,215, issued 28 September 1999).

Regarding Claim 20, Muller et al disclose the method wherein the detection uses various techniques known in the art (Column 15, lines 17-46) but they do not teach detection using sinusoidal voltammetry.

However, sinusoidal voltammetry detection was well known in the art at the time the claimed invention was made as taught by Kuhr et al who specifically teach sinusoidal voltammetry detection is more sensitive than traditional methods (Column 3, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the claimed invention

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was made to apply sinusoidal voltammetry to the detection step of Muller et al for the expected benefit of improved detection sensitivity as taught by Kuhr et al (Column 3, lines 10-25).

8. Claims 1-6, 10-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muscate-Magnussen et al (U.S. Patent No. 6,379,515, filed 19 November 1998) in view of Ensing et al (EP 0 671 626 A1, published 13.09.1995).

Regarding Claim 1, Muscate et al disclose a method for detecting two or more analytes in a sample comprising, providing a channel having affixed therein differing first and second analyte-specific binding partners located in different regions of the channel (Column 3, lines 18-48), passing a fluid comprising a sample through the channel for analyte binding, releasing the analytes from the binding partners into the fluid and detecting the analytes at a position within the channel downstream from the binding partners (Abstract; Column 15, lines 6-20; and Column 18, lines 57-59 "UV-transmitting window"). Muscate et al do not teach attachment of the binding partners to the wall of the channel. However, Ensing et al teach a similar method wherein the analyte is attached to the inner wall of the capillary thereby eliminating obstacles in the flow path and providing predicable flow conditions (page 2, lines 53-58). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the binding partners of Muscate et al by attaching them to the wall of the capillary as taught by Ensing et al for the expected benefit of eliminating obstacles in the flow path and providing predicable flow conditions as taught by Ensing et al (page 2, lines 53-58).

Regarding Claim 2, Muscate et al disclose the method wherein the analytes are not labeled (e.g. Example D1).



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Regarding Claim 3, Muscate et al disclose the method wherein the channel is a capillary tube (Abstract).

Regarding Claim 4, Muscate et al disclose the method wherein the capillary tube is a capillary electrophoresis tube (Column 14, lines 3-10).

Regarding Claim 5, Muscate et al disclose the method wherein the capillary is an etched surface (Column 13, line 66-Column 14, line 1).

Regarding Claim 6, Muscate et al disclose the method wherein the channel is etched in glass (Column 13, lines 62-67).

Regarding Claim 10-12, Muscate et al disclose the method wherein the channel has a cross-sectional diameter and width of less than 100 $\mu$ m (Column 13, lines 55-56).

Regarding Claim 13, Muscate et al disclose the method wherein the analytes comprise at least three different analytes (i.e. 10 different analyte-specific receptors, Column 3, lines 45-48).

Regarding Claim 14, Muscate et al disclose the method wherein the binding partners are antibodies, binding proteins or nucleic acids (Column 6, lines 56-65).

Regarding Claim 15, Muscate et al disclose the method wherein the binding partners are nucleic acids (Column 6, lines 56-65).

Regarding Claim 16, Muscate et al disclose the method wherein the passing a fluid is induced by a pressure difference (Column 14, lines 44-48).

Regarding Claim 17, Muscate et al disclose the method wherein the passing of fluid comprises electro osmotic flow (Column 14, lines 38-44).

Regarding Claim 19, Muscate et al disclose the method wherein detecting comprises absorbance spectroscopy (Column 14, lines 30-34).

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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BJ Forman, Ph.D.  
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Art Unit: 1634  
June 27, 2005